



Medical Products Group

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April 21, 2005

Division of Dockets Management (HFA -305)
Food and Drug Administration
5630 Fishers Lane - Room 1061
Rockville, MD 20852

RE: *Reporting of Adverse Events to Institutional Review Boards*
[Docket 2005N-0038]

Dear Sir or Madam:

Abbott Laboratories submits the following comments in response to FDA's request for comments on the "Reporting of Adverse Events to Institutional Review Boards" published in the Federal Register on February 8, 2005 at 70 FR 6693.

We support the comments submitted to Docket 2005N-0038 by the association AdvaMed, the Advanced Medical Technology Association. FDA's current Investigational Device Exemptions (IDE) regulations (21 CFR 812) provide appropriate direction for the reporting of adverse device events to IRBs during device trials. The device regulations clearly and consistently rely upon one description in terms of reporting requirements. It is the reporting of unanticipated adverse device effects. Further, sponsor and investigator roles in reporting of unanticipated adverse device effects are clearly delineated in the regulations (21 CFR 812.150(b)(1) for sponsors and 21 CFR 812.150(a)(1) for investigators). For these reasons, we recommend against making any changes to the current IDE regulations.

Thank you for the opportunity to provide these comments. Should you have any questions, please contact me at (847) 937-8197 or by facsimile at (847) 938-4422.

Sincerely,

April Veoukas, J.D.
Associate Director, Regulatory Affairs
Medical Products Group
Abbott Laboratories

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